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In search of the missing hand of ‘collaborative action’: Evidence from the Indian medical device industry

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Abstract

Some emerging countries have made significant progress in developing local pharmaceutical and biotechnology but had less success in building medical device industries. This paper explores the weak development of local medical device industries by analysing the contrasting evolutionary trajectories of Indian healthcare technology sectors. The Indian pharmaceutical and biotechnological industries have emerged as leading global suppliers of generic drugs and vaccines, in marked contrast to the medical devices industry. This paper reveals that weak collaborative linkage between medical device manufacturers and the Indian health system, largely absent systemic and cross-sectoral linkages, and weak communication between industry and government policy makers have become a huge barrier to the development of the Indian medical device industry in the contemporary neo-liberal environment. The weak connection between technology and industrial policy and healthcare policy objectives has severely hampered both development of national technological capabilities and the creation of affordable healthcare.

Key words: India, healthcare, medical devices, capabilities, pharmaceuticals, biotechnology

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1.0 Introduction

The provision of affordable and appropriate healthcare in developing countries is a key part of global development goals, including the Sustainable Development Goals (SDGs). There are three key integral industrial pillars of modern healthcare technology systems; drugs, vaccines and medical devices. Over the last decades, concerted research, policy and practice efforts have been directed towards drugs and vaccines with the primary objective of making these available and affordable to poor people in developing countries. These efforts have included the establishment of private-public partnerships and innovative supply programmes (Kale et al., 2013). Some emerging countries have shown remarkable success in the development of national technological and industrial capabilities for manufacturing vaccines and drugs. Strong evidence exists that national capabilities have significantly contributed to the reduction of health care costs in developing as well as developed countries (Srinivas, 2006; 2012; Gehl-Sampath, 2010). Healthcare policy researchers argue that “a strong national capability for both technological and social innovation in developing countries represents the only truly sustainable means of improving the effectiveness of health systems” (Gardner et al., 2007:1052). However, WHO reports highlight that developing countries have struggled to develop and manufacture medical devices appropriate to the national context and local affordability (2010, 2012). They rely on imported medical devices that are often costly or unsuitable for local conditions and endanger the lives of patients, health workers and communities (Cheng, 2007, WHO, 2012).

The contrasting development of different healthcare industries raises questions for scholars of industrial catch-up and innovation. The literature on capability development suggests that the specificity of processes through which new medical devices are generated have received much less attention than other key health care industries (Geljins et al., 2001). A wider understanding of the factors that influence access to medical devices in developing countries, and a better assessment of barriers that hinder this process, are essential for achieving the objective of inclusive healthcare and ensuring basic services for health care interventions (WHO, 2012). This paper endeavours to examine this challenging domain.

The emergence of Indian research and manufacturing capabilities in pharmaceutical and biotechnology made a significant impact in facilitating access to affordable and appropriate drugs and vaccines for populations of developing countries. But lack of similar growth in the medical device industries (MDI) has contributed to a growing mismatch in India and other developing countries (WHO, 2010). This contrasting evolution of technology systems provides an appropriate setting to unpack policies and institutions that help or hinder the development of healthcare industries in resource constrained developing countries.

This paper uses primary and secondary source data to analyse the development of India's healthcare industrial sectors. It presents a complex picture of lack of collaborative action concerning the medical devices sector. By collaborative action, we mean organised reflective public policy activities to support capability development between myriads of different public and private institutions and organisations along a wide spectrum: public to

private. There are three major weaknesses. First, complex nature of technologies, absence of research ecosystem and lack of strong domestic purchasing power act as a disincentive for local firms and entrepreneurs. Second, the 'disconnect' between healthcare objectives and industrial and technology policy includes a governance vacuum concerning appropriate regulation. The inability of policy makers to grasp complex technologies and establish appropriate supportive institutions and the inability of the Indian medical device firms to clearly communicate their needs to the government led to the neglect of the industry. Third, lack of communication among different key stakeholders has roots in the disorganised public health system, the absence of linkages between manufacturers and practitioners and complexity of knowledge associated with the development of medical devices. Improvement in public policy requires acceptance of these weaknesses and of the technological and industrial specificity of medical devices.

The paper proceeds as follows. Section two describes our research methodology. Section three introduces the framework of local technological capabilities for healthcare industries, presents main characteristics of the global medical device industry, and key differences between medical devices and pharma-biotech industries. Section four details evolution of Indian pharmaceutical, biotechnological and medical device industries. Section five presents an analysis of capability development processes in the Indian pharmaceutical and biotechnology industries compared with the medical devices industry and highlights key findings of this research. Section six concludes.

2.0 Research Methodology

Using national systems of innovation (NSI) theoretical framework, this research examines key factors that shaped the evolution of the Indian pharmaceutical, biotechnology and medical device industries. First, a comprehensive literature review and secondary source data analysis were carried out to understand the current situation of the Indian medical device industry, focused on issues related to financing, regulation, market and R&D infrastructure. These data were analysed together with summarised comparative data from the authors' previous extensive research on the pharmaceutical and biotechnology sectors, and the results presented in section 4. This analysis facilitated preparation of primary data collection.

In the second stage, primary data were collected by conducting interviews with industry association presidents, regulators, leading scientists, bio-medical engineers working in premier Indian research institutes and senior managers from Indian pharmaceutical, biotechnology and medical device firms. 25 interviews were conducted and transcribed. The interview guides focused on the current status of healthcare industries in India, technological opportunities, regulatory frameworks, key stakeholders and various government initiatives to promote healthcare research and manufacturing in India. For the most part, open-ended questions and semi-structured interview schedules were used to collect different stakeholders' experiences, observations, opinions, and desires. Further secondary data were collected from business journals, annual reports, industry analyst reports and the Indian newspapers. Empirical evidence was analysed using analytical techniques such as pattern

matching (Yin, 1994) and creating codes based on the theoretical framework. The strategy of pattern coding was used to unpack the role of policies and institutions in the development of Indian healthcare technology systems.

2.1 National Systems of Innovation (NSI)

Since the 1980s the concept 'National System of Innovation' (NSI) has gained prominence to highlight the interrelations between technological development and the institutional embeddedness of organisations (Lundvall et al., 2002). The NSI framework is based on the tenet that successful industrial development is intimately linked to a country's capacity to acquire, absorb, disseminate, and apply modern technologies; a capacity embodied in institutional interactions and learning. Complex interactions among stakeholders can effectively and efficiently facilitate the emergence and development of new technologies and industries. Cimolli et al., (2006: 5) argue that 'in a fundamental sense, institutions and policies addressing technological learning have to do with the construction of national systems of production and innovation'.

In this tradition, some researchers have focused on analysing the characteristics of the NSI in developing countries (Lundvall 1992; Nelson, 1993). The NSI framework has been used to explain the process of innovation and technological capability development at national, regional and sectoral levels. Metcalfe and Ramlogan (2008) citing Niosi et al., (1993: 212) provide a synthetic summary of the meaning of NSI as "the system of interacting private and public firms (either large or small), universities and government agencies, aiming at the production of science and technology within national borders. Interaction among those units may be technical, commercial, legal, social and financial, in as much as the goal of the interaction is the development, protection, financing or regulation of new science and technology".

This definition illustrates that the learning processes involved in technology capability development are contextually embedded in elements lying inside and outside firms, and in the dynamic interplay between those elements. The process entails interactions among many different types of knowledge that are embodied in key stakeholders and knowledge networks. These include internal actors such as scientists working in research laboratories, managers who oversee production, strategy and marketing, other actors operating throughout the value chain; and external actors including government policy makers and regulators; as well as industrial associations and lobby groups. To understand the dynamics, Malerba (2004) suggested three key building blocks: (i) the knowledge, technological domain, and boundaries; (ii) actors, relationships and networks; and (iii) institutions. This perspective stresses the central role of knowledge in innovation and highlights the significance of heterogeneous actors and institutions such as users, suppliers, non-firm organizations, government agencies, local authorities in influencing the rate of technological change, the organisation of innovative activity and performance. It acknowledges the need to go beyond public delivery and state initiatives, and the importance of public action and participation in the process of change (Drèze and Sen, 1989, p. 259). Here public refers to the substantial areas of organised economic and social activity falling beyond the state and private sectors: the associations, agencies, foundations and enterprises that are independent of government and that exist to pursue

social purposes. To emphasise that we focus on public action in this way we use the term 'collaborative action'. We use the term 'collaborative action' in its generic sense of working together towards a common goal. We use the NSI framework to recognise the complexity of interests, multiple actors and possible mechanisms of action, all of which influence how actions play out. It provides a means to include that variety of actors involved in purposive action contributing towards the development of national technological capabilities. These characteristics suggest that to understand technological capability development and change, it is necessary to study the policies, institutions and actors that influence the accumulation of knowledge and the nature of competition in the industry and the way they interact. Building on these characteristics, Consoli et al., (2016:21) highlight the benefit and usefulness of the innovation system approach to study of the medical device industry. Nelson (2003) suggests that the distributed nature of technology development in the medical device entails that the problems are created and solved by the multiple actors within different organisations ruled by distinctive knowledge and incentive systems. In this context, Consoli et al., (2016) show that innovation system approach allows to bring together an analysis of knowledge, technology; actors, relations, networks and institutions in a coherent and systemic way, thereby highlighting 'system making' connections between a set of the components that ensure the flow of feedback. As a result, NIS provides a theoretical framework for analysis of contrasting evolution trajectories in the Indian healthcare technology systems.

3.0 Local technological capabilities and innovation systems

Healthcare technology systems constitute an indispensable part of any inclusive development agenda. Many developing country governments have policies to ensure access to inclusive healthcare by developing local technological capabilities in the manufacturing of medicines, vaccines and medical devices. Bell and Pavitt (1993:167) define technological capabilities as "the stock of resources needed to generate and manage technical change, including skills, knowledge and experience and institutional structures and linkages". The early work on technological capabilities has been further developed with studies of catch-up in the East Asian economies. It further gained prominence with the understanding that industrial sectors have a set of institutions and organisations that differ across sectors and influence the way technological capabilities are accumulated and firms compete (Simonetti et al., 2016). Healthcare technology systems represent a typical example of the distinctiveness of sectoral institutions that shape technological capability development. Healthcare industries are perceived as research focused and supply driven to a much greater degree than other manufacturing sectors. There is significantly higher spending on R&D than in many sectors and the progression of science and basic technologies impacts in fundamental ways on the evolution of products and processes (Henderson and Cockburn, 1996). Chataway et al. (2007) point out that collaborative interaction within public policy in some countries and with health systems in others is a key determinant shaping healthcare industry evolution.

Admittedly, the technological capabilities underpinning healthcare technology sectors are complex and create challenges of resources and knowledge for policy makers. Research on technological capabilities in health technology sectors has tended to focus on pharma-biotech industries and on India, China, Brazil and South Africa

(Rezaie et al., 2012). This literature has generally neglected the specificity and the complexity of medical technology sector development in developing countries. With the exception of a recent WHO (2010) study, the development and availability of affordable and appropriate medical devices in developing countries have been under-researched. Overall, those studying technological capability development have not paid attention to the factors responsible for the absence of capabilities for development and manufacture of high-tech medical devices of firms in the South (Kale, 2010; WHO, 2012). In such an environment, collaborative action becomes a major element of public policy initiatives. Collaborative action goes beyond one-off state, public, private and public-private type initiatives if technological and industrial capabilities are to be developed quickly enough for rapid catch-up.

Healthcare technology systems

Pharmaceuticals, biotechnology and medical devices are all health technologies used to treat, alleviate and cure diseases; play key roles in modern health care; require regulatory systems; and need an effective supply chain. These sectors depend on integration of multiple complex knowledge bases for the development of innovative products and collaboration with hospitals, universities and public research institutes form the core part R&D strategies. The structure of demand includes the important role of the state through public procurement of essential medicines, vaccines and devices for the health system and, especially in low-income countries, international donors play a major role in the purchase of key healthcare technology products (Simonetti et al., 2016). However, key differences exist between the dynamics and complexities of the innovation process in medical device industry including the nature of R&D and the public policies that affect the industry (Medical Technology in Australia, 2012; Kahn, 1991) (see Table 1). In the medical device industry, innovation is significantly driven by small entrepreneurial firms while large firms dominate certain segments such as medical imaging where devices are complex and costly. Small firms are mainly led by medical engineers, clinicians or surgeons with strong user influence over innovation. They are often bought by large firms after innovation is introduced in the market. Further explaining the dominance of small firms in a certain segment of the market, Kahn (1991:6) suggests that ‘an evaluation of the market before a device is diffused into clinical practice can grossly undervalue the technology to a degree that only very small companies would find the prospects interesting’. Fleck’s analysis of robotics innovation as ‘innofusion’ allows us to differentiate medical devices from the very science-oriented pharma and biotech sectors (Fleck, 1988). Fleck shows how important incremental and highly knowledgeable practitioner users were for successful innovation in highly multi-engineering (electrical, electronic, mechanical, information) environments.

Table 1 Differences between medical devices and pharma-biotech drugs (Medical Technology in Australia, 2012)

	Medical devices	Pharma-biotech
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Industry composition	Over 80% small and medium-sized companies and few MNCs Wide variety of products and applications – from thermometers and bandages to pacemakers to x-rays	Dominated by large MNCs, Two segments: Generic and branded innovative drugs
Product development	Incremental improvement and ‘innofusion’ based on user driven innovation Continuous innovation and iterative improvements based on new science, technology, and materials, Majority of new products bring added functions and clinical value based on incremental improvements, Designed to perform specific functions and approved on the basis of safety and performance, Many products developed by doctors or nurses and design capabilities play a vital role (that is, users are innovators).	Still dominated by linear model of innovation Extensive research and development of a specific compound or molecule; takes several years for a new drug to enter the product pipeline Less complexity in the sense of a single dominant knowledge domain (chemical or biological) Products are usually in the form of pills, solutions, aerosols ointments Product development by discovery, trial, and approved on basis of safety and efficacy Products developed in laboratories by chemists and pharmacologists
Market dynamics	Short product life cycle and investment recovery period (typically 18 months on market)	Long shelf lives
Mechanism of action	Most act through physical interaction with the body or body part	Products are administered by mouth, skin, eyes, inhalation, or injection and are biologically active; effective when absorbed into the human body. Often act systemically on the entire body
IPR concerns	Little patent linkage possible. Data exclusivity is important.	Intensive patent protection, including data exclusivity

Medical devices: Global industry and market structure

Medical devices include everything from highly sophisticated computerised medical equipment down to simple wooden tongue depressors (WHO, 2010). The MDI is characterised by its diversity of devices, applications and underlying knowledge bases. There are over 10,000 different types of medical devices ranging in complexity, price and life span: from in-vitro diagnostics, imaging instruments, single use devices, surgical instruments, implants and all electro-medical equipment.

The global medical device market was valued at \$164 billion US in 2010, growing at a compound annual growth rate (CAGR) of 6% since 2000 (WHO, 2012). The industry comprises over 27,000 companies. In 2009, the USA constituted 41% of the world's total market, followed by Japan (10%), Germany (8%) and France (4%) (WHO, 2010). According to the WHO (2010), 85% of medical devices are manufactured in the USA, Japan and European Union countries. Firms from advanced countries dominate R&D and production. Seven out of the top ten firms and all but 11 of the top 30 companies have US headquarters (WHO, 2012). The top 30 firms account for 89% of all global revenue. (WHO, 2010), collectively spent 9% of their sales revenues on R&D in 2010; up 2.5% from 2008 (WHO, 2012). A string of evidence points to medical device companies developing devices catered to users in advanced countries (WHO, 2012). Healthcare priorities in advanced countries now focus primarily on ageing and the management of chronic diseases, differing markedly from those in developing countries (Cheng, 2007).

The medical device industry mismatch in developing countries

The diversity and scale of health challenges in developing countries suggest a huge role for medical devices but only 13% of manufacturers are in developing countries (WHO, 2012). Firms are weak and focused in the low-tech part of the sector. Many developing countries depend on imports, not national production to satisfy their healthcare needs. The leading suppliers of medical devices to Africa are Germany, France, the United States, China, and the United Kingdom. Emerging countries such as India, China and Brazil export medical devices to other developing countries but these countries dominate low-tech segments while advanced countries dominate high-tech segments (WHO, 2012).

Resource constraints, along with the environmental and operating conditions - including climate, access to water, electrical supplies and transportation conditions – add to the constraints affecting the use of medical devices in developing countries. A World Bank review of the Bank's investment in medical devices from 1997 to 2001 provides clear evidence of this mismatch. The review found cases where, "about 30% of sophisticated equipment remained unused, while those in operation have 25% to 35% equipment downtime because of weak capacity to maintain the equipment" (World Bank, 2003). Similarly, a recent WHO (2010) report shows that more than 50% of devices remain unused in developing countries due to structural and cost factors.

The mismatch between the local need for medical devices and their availability and effective has been little studied (WHO, 2010). This paper focuses on the Indian healthcare technology sectors to analyse policies and institutions that help and hinder the development of these sectors in developing countries.

4.0. Evolution of the Indian healthcare technology sectors: Pharmaceutical, biotechnology and medical device industries

This section presents data to map the key policies and institutions shaping the evolutionary trajectories of three Indian healthcare industries. Short reviews of the pharma and biotech sectors serve to provide a comparative framework allowing us to evidence the relative weakness of MDI evolution.

4.1 Indian pharmaceutical industry

Globally, the Indian pharmaceutical industry is the twelfth largest in terms of value and third in volume with a ten per cent share of the global market (OPPI, 2014). It is a highly successful science and technology based industry, with consistent growth aided by strong government industrial policy. The Indian pharmaceutical industry has evolved steadily with sufficient capability to ensure national self-sufficiency. The industry is characterised by a low degree of concentration; a large number of firms with similar market shares, a low level of R&D intensity ratios and a high level of brand proliferation. The changed policy regime of the 1990s transformed the Indian pharmaceutical industry's 'ways of working' and the industry grew rapidly post 1990s, with an average industry growth rate of 15% for bulk drugs and 20% for formulations (OPPI, 2001).

4.1.1 Evolution of the Indian pharmaceutical sector

Since independence in 1947, the Indian government developed a series of public policy initiatives to build the national pharmaceutical industrial base with the aim of making drugs available to poor populations at affordable prices.

Fig. 1 Evolution of Indian pharmaceutical industry (Kale, 2010)

The pharmaceutical industry has evolved through three phases, each characterised by different policy regimes and industrial response (Fig 1). In the first period to 1970, the industry had relatively weak production capabilities. In the second period (1970s to early 1990s), industrial output grew remarkably. In the third phase, from the 1990s onwards, the industry grew more than three times faster than during the 1980s (Kale and Little, 2007).

Pre-independence, Indian domestic production was tiny. There were less than 10 registered producers of Western-type pharmaceutical products in 1915 and 30 in 1947. After independence, the Indian government gave priority to pharmaceuticals and both private and public investment encouraged. In 1954, the government set up a public sector pharmaceutical firm; Hindustan Antibiotics Limited (HAL) to produce penicillin and sulfa drugs and in 1961 set up another firm; Indian Drugs and Pharmaceuticals Limited (IDPL). Several foreign multinational firms invested in India through the 1950s and 60s and until the 1970s these firms dominated the local market. Some MNCs set up marketing and distribution facilities only, importing bulk drugs from their overseas manufacturing facilities. In response to government pressure against the import of finished products, MNCs set up formulation units, restricting imports to bulk drugs. The Indian government set up a network of pharmacy colleges, universities and research institute to support domestic pharmaceutical industries. For example, in 1951 the government established the Central Drug Research Institute (CDRI) with extensive drug development infrastructure. The CSIR system has 20 other laboratories engaged in some form of pharmaceutical R&D. Together, this public sector, research institutes and MNCs developed the basic knowledge base required for the industry and emerged as the main source of industrial entrepreneurs a decade later. Still, the Indian population was largely dependent for the supply of medicines on imports from MNCs. The cost of these medicines was out of reach for the majority, and thus the Indian government made strategic industrial and regulatory policy changes in 1970.

Government adopted weak patent laws to allow Indian firms to reverse engineering products and this laid the foundation for the strong domestic industry. In 1978, the government launched a new Drug Policy with more protection for domestic firms. The Drug Price Control Order (1979) empowered the government to fix maximum sales price of 347 essential drugs which played an important role in driving local process R&D innovation. Together these infant industry initiatives infused life into the Indian pharmaceutical industry.

Post-1990 the Indian government liberalised the economy and opened the pharmaceutical sector to MNCs. India emerged as a cheap and efficient supplier of bulk drugs and formulations to the developing and developed world. To improve local manufacturing, the Indian government made Good Clinical Practices (GCP) and Good Manufacturing Practices (GMP) legally binding for all manufacturers. In 1995, the government adopted a stronger patent regime in compliance with TRIPS (Trade Related Intellectual Property Rights) agreement. Recognising the imperative to strengthen R&D, the Government set up schemes to encourage collaborative action between research institutes and industry, in 1995 launching the New Millennium Leadership Technology Initiative (NMLTI) programme to bring together industry and academia to synergise the facilities and competencies of publicly

funded R&D institutions, academia and private industry to develop treatments for local populations. In the same year, the Indian government set up the National Institute of Pharmaceutical Education and Research (NIPER) as a centre of excellence in pharmaceutical science and technologies, education and training. In the Indian pharmaceutical industry, there was collaboration as well as a contestation between industry associations representing MNCs (Organisations of Pharmaceutical Producers of India, OPPI) and domestic firms (Indian Drug Manufacturing Association, IDMA) that helped engage a diverse set of stakeholders and shape government policies (Watkins et al., 2015).

In summary, government public policy intervention and regulatory changes brought a dynamic response from Indian pharmaceutical firms which in turn made a huge contribution to the supply and access to medicine to populations in developing countries.

4.2 Indian biotechnology industry

The Indian biotechnology industry is among the top 12 by a number of biotech companies and is a lead producer of affordable vaccines globally. In 2013, the industry registered a 15% growth rate generating revenue of US \$ 400mn (Biospectrum, 2013). Since 2000, the Indian biotechnology industry has shown high growth rates based on process R&D capabilities, cheap production costs and strong export performance. From 2002-2007 the industry grew at a CAGR of 30%, followed by growth of 15% CAGR during 2005-2010. Since 2003 exports have grown at 26% CAGR (Fig. 2).

Fig 2 Growth in the Indian biotechnology industry (ABLE-Biospectrun survey, 2003-2013)

4.2.1 Evolution of the Indian biotechnology sector

The Indian biotechnology industry has evolved through three phases; initiation (1975-85), development (1985-95) and growth (post 1995). Fig 3 maps the key elements of each phase.

In the late 1970s, the Indian government identified biotechnology as a tool to advance the growth of agriculture and healthcare and started planning for growth. India's Sixth Five Year Plan (1980-85) was the first policy document to cover biotechnology (Chaturvedi, 2005). In 1982, the government set up an official agency, the National Bio-Technology Board (NBTB), to lead biotechnology development and further initiatives were launched in the sixth and seventh (1986-1990) five year plans. In 1986 NBTB was dissolved and the Department of Biotechnology (DBT) established with wide powers to coordinate development of different competencies in a variety of scientific disciplines (Ramani, 2001). DBT took the lead to create new national institutions dedicated to biotechnology research, the Centre for Cellular and Molecular Biology (1982), National Institute of Immunology (1986), and International Centre for Genetic Engineering and Biotechnology (1987).

Fig. 3 Evolution of the Indian biotechnology industry (Source: Author calculations)

In the 1990s the Indian government noticed a lack of funding for biotechnology entrepreneurs, with traditional financial institutes sceptical about funding uncertain new technology. In 1994, the DBT with the Industrial Bank of India (IDBI) established the Biotech Consortium India Limited (BCIL) as a public limited company to function like a venture capital firm and promote the creation of new firms through funding and simultaneously building the complementary competencies needed to manage top research based firms (Ramani, 2001). BCIL was tasked to guide start-ups, find adequate financial avenues and arrange technology transfers. State agencies such as the Department of Scientific and Industrial Research (DSIR), Department of Science and Technology (DST), the Indian Council of Agricultural Research (ICAR) and the Indian Council of Medical research (ICMR) have all established biotechnology programmes (Chaturvedi, 2005) and since 1990 have all emerged as key investors in biotechnology (fig 4).

Fig 4 Budgetary allocations to the Department of Biotechnology (millions of USD) (Source: Ministry of Finance, Government of India)

After 1995, the specificity of the sector was recognised by government initiatives that generated interest among Indian entrepreneurs and dedicated biotechnology firms such as Shantha Biotech, Bharat Biotech, Strand Genomics emerged. These Indian firms have been in the forefront of developing high quality vaccines affordable to local populations. Bharat Biotech, for example, has priced its indigenously developed Rotavirus vaccine at the US \$1 per dose, the cheapest in the world. Prominent among India's notable achievements in modern biotechnology in recent years is the development of a recombinant hepatitis B vaccine, human insulin, erythropoietin, granulocyte colony-stimulating factor, interferon and streptokinase.

In the case of biotechnology, the collaborative action was catalysed by industry associations purposefully creating linkages with international organisations, participating in international conferences and employing consultancy companies to prepare research-based reports on future growth and policy recommendations. Further, industry associations engaged with policy makers and civil society organisations to educate and formulate regulatory and technology policies suitable to the needs of their members (Newell, 2003).

In summary, from the 1980s the biotechnology industry grew based on the coherent support and policies of the Indian government, together with the entrepreneurship shown by Indian scientists. Financial support from the Indian government, development of research infrastructure, regulatory support, and local entrepreneurship, has built a strong national biotechnology industry.

4.3 The Indian medical device industry

The analysis just presented allows us now to evidence the relatively weak evolution of public policy and the medical device industry. Our data suggest both weak public policy development over decades and overall lack of collaborative action between public and private actors and institutional systems.

The Indian medical device industry is estimated at the US \$ 4.5 bn in 2012, growing at the rate of 14% per annum (WHO, 2012) but the industry is not well documented and estimates of its size vary significantly. There are about 14,000 medical devices marketed in India. Diagnostic equipment accounts for the largest portion of the medical device market, with an almost 30% annual average growth rate (Deloitte, 2010).

Fig. 5 Market distribution of Indian medical device industry for 2008 (Deloitte, 2010)

India has become increasingly dependent on imports from countries like the US, Japan, the UK, France, Finland and Germany (WHO, 2012). This dependence has roots in the complex nature of technology systems, the absence of technological capabilities in local industry and a missing research ecosystem. Commenting on the state of the Indian medical device industry Kamath (2010:10) comments,

“the words India and medical technology are seldom used in the same sentence. An indigenous medical device industry has been virtually non-existent. Local players, with some exceptions, have struggled to shed the ‘low-tech, low quality’ tag. For instance, doctors faulted local pacemakers for being too bulky and difficult to implant with leads (that connect the pacemaker to the heart muscle) fracturing easily”.

4.3.1 Evolution of the Indian medical device sector

The Indian medical device industry is highly fragmented with few domestic manufacturers (Datta et al. 2013). Also, in contrast to the Indian pharmaceutical and biotechnology industries, the evolution of the Indian medical device sector has seen little ‘smart’ government involvement in terms of industrial and regulatory policy. Figure 6 gives key milestones. There have been three major periods.

Fig 6 key milestones in evolution of the Indian medical device industry (Source: Author calculations)

Before 1990

Before 1990, a majority of the Indian population had very limited access to medical devices: medical device market size in 1985 totalled US\$ 280 million (Ramani and Rameseshan, 1989). The prevailing rates of tariff on medical devices were 40 to 60 per cent until 1990, though 'life saving' medical devices could be imported duty free (Mahal and Karan, 2009). The few local firms were predominantly focused on non-invasive medical devices and orthopaedic implants. The first major achievement for the Indian industry was the indigenous development of the Jaipur foot; a leg and foot prosthetic made of locally available soft materials, by craftsman Ram Charan Sharma and surgeon Pramod Sethi in 1968. The co-inventors then joined the Bhagwan Mahaveer Viklang Sahayata Samiti (BMVSS) to develop a business model that leveraged approximately 60% of total funding from donations, 30% from government support with the remaining 10% from earned income. In 1975 BMVSS started offering free prostheses in India. This success spurred the establishment of the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMSCT) in 1976. This hospital was established with the aid of the Royal Family of Travancore and had a biomedical technology wing dedicated to the development of medical devices, proving to be a significant step in laying the groundwork for future development of the Indian medical device industry. A Ramani, Head of R&D at TTK (Tiruvellore Thattai Krishnamachari) Healthcare explains,

Virtually every leading Indian research institute worked with Sree Chitra on the development of the heart valve. The whole concept of clinical trials for medical device product was unknown and we initiated those processes. This institute was started with the idea of developing biomedical products in India.

(Interview data, May 2014).

Dr Valiathan, a cardiac surgeon, returned from the US to head the institute with the aim to develop an indigenous heart valve in India for rheumatoid heart disease patients. This disease is closely associated with overcrowded, poor living conditions and in India was found to be predominant in children. There was a growing need for durable, affordable mechanical heart valves but their supply was controlled by MNCs and unaffordable to most. The key challenge was the lack of a local biomedical engineering industry, further compounded by the absence of collaborative networks of research institutes and research hospitals (Valiathan 2008). Local cultural beliefs (which rule out porcine and bovine transplants), the absence of regulation (with consequent challenges to gain market acceptance) and lack of an effective supply chain created more complexities. In 1976 Dr Valiathan initiated the project and to bridge knowledge gaps, he collaborated with the National Aerospace Laboratory and Vikram Sarabhai Space Centre (later renamed Indian Space Research Organisation - ISRO). After 12 intense years, the Sree Chitra institute successfully developed the 'Chitra' valve and transferred its technology to TTK healthcare, a local Indian firm, for production and marketing in India and in some other developing countries. This development of a mechanical heart valve and the consequent effort to establish a collaborative research network marked the emergence of indigenous technological capability in high-tech medical device development (interview with Mr Pitre, CEO of orthopaedic trauma product company, 2014). Building on these efforts the multi-disciplinary team at the biomedical wing of Sree Chitra Institute developed and transferred a series of devices including a blood bag, disposable oxygenator, cardiectomy reservoir, vascular graft and dental composites. However, the success of the

Sree Chitra Institute was not replicated by private industry and other research institutes. Major market segments were dominated by the MNCs and local firms struggled to compete, due to lack of trust among customers, the absence of regulations and high investment cost. Weak industrial development meant that the MDI was not well positioned for economic liberalism.

Post 1990: Economic liberalisation and MNC domination in local markets

After the policy of economic liberalisation began in India in the 1990s, the increasing size of the healthcare market gave a boost to domestic firms but also led to increased imports. The Indian government significantly reduced import tariffs on medical devices (to 15 to 30%) and de-licensed imports. Growing at 15-20% a year, India's market for medical devices reached \$680 million in 1995 (Kader and Priestley, 1997). In 1995, of about ninety local firms, 22 dominated production, joint ventures and collaboration with overseas firms. But there was a significant increase in imports. Between 1994 and 1996 US exports to India increased by 19%, constituting a 40% share of the medical device market (Kader and Priestley, 1997). Increased imports did not resolve issues of affordability and appropriateness. Dr Valiathan, a leading cardiovascular surgeon and main contributor to Sree Chitra heart valve comments,

We are compelled to import 90% of high-end instruments and devices for our hospitals at high cost and replace them every 3-5 years at still higher cost. This pushes up the cost of specialised care in cardiology, neurology etc and makes it inaccessible to the majority of Indians. MNCs estimate their Indian market as 200 million who can pay – conveniently ignore one billion who can't.

(Interview, May 2014)

MNCs were primarily involved in the distribution of medical devices, entering the domestic market either by employing local agents as distributors or by setting up a sales and distribution presence. Citing lack of availability of trained bioengineers and absence of support industries MNCs preferred to import rather than manufacture locally (interview with VP, India of MNC, May 2014).

Liberalisation policies led to imports dominating local production. Indian industrial policy indirectly rewarded imports rather than manufacturing firms operating in India. For example, the Indian government provides import duty exemption for equipment and technologies that are not available in India but charges custom duty for imported raw materials required to manufacture those products locally. As a result, it is cheaper to import final products rather than import subparts to assemble in India. A CEO of diagnostic company complains:

We have to import the raw materials after paying duty and the finished products are imported duty free.

(interview, May 2014)

However, Indian firms did emerge as a significant force in the low-tech medical device market for furniture and other instruments, not used in treatment. Essential ancillary instruments for the hospital industry constitute a substantial part of medical device production in India. Indian manufacturers export almost 65-70% of production to other developing countries (WHO, 2012). During the period 2001 to 2010 export of medical devices has grown at more than 10 % per annum (Datta et al., 2013). Some experts point to the small size of domestic MDI and the low-tech nature of devices as the main reason for the overall neglect of the industry. A head of a local diagnostic company comments,

Pharma was established in India for decades; their R&D picked up momentum after India signed the WTO agreement and patent regime changed. Biotech had novelty and glamour and government set up a department, which promoted it aggressively. Devices suffered from neglect by the medical profession, technologists, industry and government. Poor investment in R&D facilities and absence of 'Medical Device legislation' is hampering the growth of the Indian medical device industry.

(Interview, June 2014)

Due to small size of the local industry, its low-tech nature and the dominance of MNCs, no sector specific industry associations existed till 2009 which together with neglect from umbrella industry associations, has held back the education of policy makers and shaping of policy initiatives to meet the needs of local medical device manufacturers. The CEO of a diagnostic company highlights this neglect,

If you build enough revenues, if you build enough noise, you can lobby better. Biggest Indian medical device companies have low revenues, how much can you really lobby.

(interview extract, June 2014)

As a result, in this period the evolution of the Indian MDI was symbolized by public policy neglect with weak collaborative action to build a strong local industry. Regulatory neglect meant no Indian policy to oversee device safety. Regulatory oversight opened the door for low quality devices to enter the market and weakened Indian manufacturers capacity to export to international standards. Regulatory approval processes for high-tech products were absent and in many cases, local innovators had no idea whose approval they needed to launch a product. Mr Ajay Pitre, head of orthopaedic company suggests,

Doing the right things is not incentivised and that's why image of the country worsens. Reality is, if well-regulated industry exists, then all those who are doing counterfeit work today, will not be doing it. They would be doing right things and then there will be competition amongst right companies.

(Interview, May 2014)

The near MNC monopoly did not guarantee quality and lack of regulatory oversight created challenges in the detection of spurious devices. In 2004, this resulted in a serious incident at Jamshedjee Jeejeebhoy (JJ) Hospital in Mumbai. The JJ hospital used unapproved drug eluting stents on 60 high-risk cardiac patients. Stents,

manufactured by a Netherland based company, were not approved for use in EU markets. In 2005, the Mumbai High Court ordered the Indian government to set rules and standards for the medical device industry. This brought a new focus on the state of regulation and industrial policy for medical device manufacturing in India and gave rise to the new era.

Post-2005: Sprouts of Indian entrepreneurship and evolving regulation

Taking note of the high court order, the Indian government brought ten medical devices under the jurisdiction of the Drugs and Cosmetics Act, 1940, including cardiac stents and heart valves, later adding four more devices. However, the Drugs and Cosmetic Act and infrastructure, designed to regulate pharmaceutical and cosmetic products, was inadequate for governing medical devices due to the nature of difference in products, their action in human body and packaging. For example, the concept of sterility differs in pharma-biotech products and medical devices. A drug has to be manufactured in 'clean room conditions' requiring a certain standard of flooring, air-flow and energy requirement to minimize impurities. In contrast, medical devices can be sterilised at the point of use, even in the operating theatre and don't require the same production conditions. A leading manufacturer of cardiac products commented on the Indian regulatory system in 2014:

This industry is considered to be a pharma segment but really does not belong there. The authorities themselves are not knowledgeable about medical devices industry.

(Interview, May 2014)

The Indian government continued to reduce import duties to 12.5 % by 2004 and 5 % by 2013 which drove a sharp increase in both volume and value of imports (Mahal and Karan, 2012). In 2012, imports constituted 1.14% of global import of medical devices while the Indian export share constituted less than 0.5% of global exports (Datta et al., 2013). Total negative trade imbalance in medical devices rose steadily to reach US\$ 2.1 billion in 2010 (WHO, 2012). Imports of healthcare products grew tenfold in the 1990s and increased by a CAGR of 12.5% from 2000-2010 (Datta, et al., 2013). By 2010 there were 356 medical device-manufacturing units accounting for only 0.19% of total Indian manufacturing (Datta et al., 2013). Increasing imports evidence that in most segments Indian firms are struggling either to develop devices suitable for local use or to find acceptance for their products.

The growing local healthcare market resulted in MNCs moving away from employing local agents as distributors to set up subsidiaries or joint ventures with local manufacturers. In 2007 over 25 MNCs received licenses to import medical devices through their subsidiaries (Deloitte, 2010). Some subsidiaries were also involved in the development of innovative devices appropriate for local use. General Electric developed an ECG machine via Indian R&D, a successful case of an affordable innovation using local resources and appropriate to local conditions. GE used local technology and labour to produce a portable machine, which can withstand local infrastructure challenges and at 60% lower cost. This success received wide acclaim and generated awareness of Indian potential capabilities to create devices appropriate to developing country contexts. This led to the entry

of international funding agencies, the Wellcome Trust and Stanford University into the India medical device sector. Some initiatives were launched in collaboration with the aid of DBT and DST. For example, in 2008 the Wellcome Trust and DBT launched the 'Affordable Healthcare Initiative', with £125m of joint funding to boost biomedical research through a series of fellowship programmes and support for the development of affordable healthcare products. Building on this the Stanford-India bio-design initiative emerged in 2010; research collaboration between the All India Institute of Medical Sciences (AIIMS), the Stanford University and the DBT aimed at encouraging local entrepreneurship and promoting the development of medical devices appropriate to local conditions. This initiative achieved its first success with the development of the 'Jaipur knee', a prosthetic joint that mimics natural joint movements and costs only US\$20 compared to the \$10,000 cost of a titanium replacement (Time, 2009).

In summary, there are some few signs of emerging entrepreneurial and innovative capability growth but within a liberalisation environment where policies towards importation and regulation have brought a huge trade imbalance and constraints on local productive capabilities.

5. Analysis and discussion

Our results highlight the remarkable success of post-independence Indian pharmaceutical and biotechnology industries, the result of an approach that built innovation systems, bringing together state and other collaborative interventions that allowed co-evolution of firm innovation dynamics. Table 2 uses our primary and secondary data to present a comparative innovation systems summary analysis of the Indian pharmaceutical, biotechnology and the Indian medical device industries. It shows that the Indian pharmaceutical and biotechnology industries have been richly rewarded from smart state interventions, supportive institutions and industry associations but that the medical device industry has yet struggling to get appropriate regulatory system, nor a range of policy initiatives needed for Indian firms to develop innovative capabilities. At the same time, neither have Indian firms evolved a coherent collaborative approach that would help them accelerate building their capabilities.

The Indian pharmaceutical and biotechnology industries started with a weak base in science and production capabilities but public initiatives supported their evolution into significant providers of affordable healthcare. Evolving industrial policy regimes influenced firm level learning processes and shaped technological capability accumulation in the industries. In comparison, the Indian medical device industry has suffered from severe public policy neglect which has handicapped local manufacturers, allowed unrestricted import of sub-standard products, swamped markets with counterfeit products and created a market skewed in favour of MNCs and spurious local traders. Dr. Valiathan summarises bluntly:

"Devices suffered from neglect by the medical profession, technologists, industry and Government".

(Interview, May 2014)

What does our comparative innovation systems analysis suggest if innovative and entrepreneurial capabilities are to be transformed?

Table 2 Comparative analysis of Indian pharmaceutical, biotechnology and medical device industry (Kale, 2010)

	Indian pharmaceutical industry	Indian biotech industry	Indian medical device industry
Regulation	Established Drug Controller General of India (DCGI), enforced GMP and GLP regulations for pharma production, modified Drugs and Cosmetics Act, 1940 to improve quality of pharma products	Set up infrastructure and regulations such as Environment (protection) Act, 1986 and Rules, 1999; Recombinant safety guidelines, 1990 and Revised guidelines for safety in Biotechnology, 1994 to ensure safe and good quality products	<ul style="list-style-type: none"> - No regulation till 2005 - 10 devices regulated under Drugs and Cosmetics Act - Proposed Medical device regulation is stuck <p>Some low-tech devices such as thermometers and weighing instruments seek optional certification (ISI marking) from Bureau of Indian Standards (BIS) as a proof of quality rather than as a pre-market approval requirement. These procedures are not adequate to assure the quality of high technology devices.</p>
Research institutes, universities and hospitals	Wide network of R&D institutes working on pharmaceutical R&D Moderate collaboration between research institutes and pharmaceutical firms	Active government intervention by setting up research institutes, funding schemes and regulatory legislations Strong collaboration between research institutes, biotech firms and universities	Lack of collaborative web of industry/hospitals/academic linkages with Sree Chitra Research Institute as an exception

Industrial and technology policy	Till 1990 active government support via industrial policy; regulation and infrastructure Pharmaceutical policy 2002.	Active intervention by DST by establishing Department of Biotechnology and launching supportive technology policies	No evidence of active efforts on part of government till 2005 Import rules: raw material more expensive to import than final product Little or no attempt to shape policy toward promoting local production by MNC or by local producers Little attempt to create research ecosystem for local tech development
Access to finance	Govt launched financial schemes to support pharma R&D	Govt created access to finance through a number of policy initiatives and direct financial support to entrepreneurs.	Venture capital firms and private mentors supported local entrepreneurs, post 2012 DBT and international funders such as the Wellcome Trust and Gates Foundation.

Entrepreneurship	<p>Entrepreneurship showed by pharmaceutical distributors, scientists and managers, effective imitation strategy and reverse engineering to develop capabilities in a sequential manner</p> <p>Significant impact of local firms, and acceptance of product from large and protected domestic provided incentive to entrepreneurship</p>	<p>Government encouraged entrepreneurship by funding proposals from returned scientists Collaboration with overseas and domestic research institutes helped in development of local capabilities</p> <p>Domestic firms made vaccines accessible to local populations and emerged as a key supplier to WHO and Gates Foundation. Gradually pharma firms started entering biotech markets</p>	<p>Difficulty in initiation and MNC dominated domestic market proved disincentive for entrepreneurs</p> <p>Market acceptability; doubts over quality of products from local producers</p> <p>Capital intensive so vulnerable in volume based markets; "difficult to create first world products for third world prices"</p>
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5.1 Challenge of technological complexities and specificities

The development of medical devices is dependent on a diverse range of technological competencies that are not core to medical sciences and can be understood only in association with the surgical and medical practices in which they are utilised (Gelijns and Rosenberg, 1994). Complex hybrid technologies require integration of engineering and science knowledge bases coupled with medical knowledge from surgeon and practitioners. This style of innofusion-type innovation differs markedly from that required for pharmaceutical and biotechnology. The requirement for multi-technology skills, strong manufacturing capabilities and a user-driven innovation process demanding collaborative relationships with practitioners raised problems of technical and organisational capabilities for Indian entrepreneurs. The technological capability deficit was further accentuated in the last decade by the increasingly capital intensive nature of medical device business, creating a challenge of operating a profitable business in 'high volume but low value' developing country markets.

5.2 Challenges in framing complex public policy and supportive institutions

These technological complexities and specificities also posed challenges for the policy making process and created difficulties for the Indian government in framing regulatory, technology and industrial policies appropriate for the medical device industries. Public policy for medical devices is extremely complex compared to pharma-biotech requiring the involvement of a wider range of distinctive health institutions, regulatory institutions and industrial institutions. Involvement of public as well as private actors in issues such as foresight, experiment, new institutions, fusing capabilities and decision-making capabilities is essential (Lundvall et al., 2002). In the case of the Indian pharma-biotech industries, local private firms, research institutes, civil society organisations and industry associations worked with the government to set up industrial, trade and regulatory policies with the objective to develop national industries to better serve the needs of its people. For example, the pharmaceutical and biotech industry associations actively lobbied with the government to remove entry barriers for entrepreneurs and create incentives for national firms. The Indian government played an enabling role by protecting domestic markets and setting up supportive research networks. Timing is also a major factor explaining the sectoral differences. The pharmaceutical industry had several decades of support in a period when import substitution industrialisation was normal, so the industry could take advantage of liberalisation and continued the smart public policy in the 1990s. The biotech industry began later but in a period when public support for this new sector was normal, and Indian policy was comprehensive and collaborative. Newell (2003) documents the influence of biotech associations in shaping biotechnology policy and regulations. This two-way communication helped the government to understand the needs of local firms and set up appropriate policies. In the Indian medical device industry, the weak collaboration between industry associations, institutions and domestic firms has proved a major barrier, preventing institutionalised communication between key stakeholders. And as each decade goes by, with increasingly liberal global trade, there is a greater need for tighter and smarter public policy.

Our analysis reveals that the complex hybrid set of technologies underpinning medical device product development, failure of public and private actors to get to grips with the policy issues, and increasing pressure against national industry development, has shaped an import dependent domestic market and technologically stagnant medical device industry.

6. Conclusions

National development of technological capability in healthcare technology systems is key to increase access to effective healthcare. This paper analyses the contrasting evolution of the Indian healthcare technology sectors and contributes to the literature focused on the question: how to industrialise for health?

The paper shows, using an innovation systems approach, that dynamism of local entrepreneurs and supportive smart public policies by the Indian government led to the development of indigenous technological capabilities in the pharma-biotech industries. The Indian pharmaceutical and biotech industries experimented with strategies, formed industry associations to influence policy makers and entered advanced country markets to emerge as the pharmacy of the world. Government initiatives played a crucial role in creating the base for local firms to innovate, enter new markets, and improved prospects for affordable healthcare. However, in medical devices, industry lacked this proactive approach and was further hampered by the inability of the government to understand the complexity of technology and formulate industrial and regulatory policies. The earlier development of pharmaceuticals as an import substitution industry to provide health care, and the later public push to build a strategic biotechnology industry, was not honed and reshaped for the harder task of building a multi-pronged industry in a strongly neo-liberal environment.

This research shows that the medical device sector involves a significant diversity of knowledge base and product base which constitutes a distinctive techno-science sector. This suggests that innovation systems specifically designed and locked-into pharma-biotech cannot be cloned for medical devices. Local medical device firms need to establish R&D collaborations with research institutes and hospitals to bridge knowledge gaps and build basic technological capabilities. These R&D networks would assist in developing an ecosystem. Local innovative medical device firms could focus on emerging countries markets to build opportunities to upgrade their technological capabilities. Strong public policies and collaborative actions are needed to establish appropriate regulatory, industrial and trade policies to invest in coherent healthcare systems.

Our findings have implications for innovation systems and for contemporary public industrial and health policies in both the developing and developed world. First, we highlight the significant role of entrepreneurs and firm dynamics

for driving growth in industrial sectors. Second, we show that policy for affordable and appropriate healthcare needs to be deliberately tied with technology and industrial policy.

The Indian government has the public policy capabilities to support the development of major new industries. However, public policy for the medical devices industry has not yet been successful. Different public policy initiatives are required. A major trans-institutional and public private initiative along the lines of the Biotechnology initiative with a more diverse range of relevant stakeholders would be a key advance to build a sector whose innovative capabilities are key for health improvement and social and economic development. If the Indian government, and its public and private sector collaborators, were to succeed in supporting the building of national innovative capabilities in this sector, it would both: enhance its capabilities in growing technologically complex industries with strong social and economic linkages and complex communication across multiple actors and institutions; and have a huge impact on the affordability of health systems nationally, and globally.

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